

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER ASZD-P01-708
		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/516423
INTERNATIONAL APPLICATION NO. PCT/SE03/00857	INTERNATIONAL FILING DATE 27 May 2003	PRIORITY DATE CLAIMED 31 May 2002
TITLE OF INVENTION IMMEDIATE RELEASE PHARMACEUTICAL FORMULATION		
APPLICANT(S) FOR DO/EO/US Alami et al.		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
- ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
- ☐ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
- ☒ The US has been elected (Article 31).
- ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - ☐ is attached hereto (required only if not communicated by the International Bureau).
 - ☒ has been communicated by the International Bureau.
 - ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
- ☐ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
 - ☐ is attached hereto.
 - ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
- ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - ☐ are attached hereto (required only if not communicated by the International Bureau).
 - ☐ have been communicated by the International Bureau.
 - ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - ☒ have not been made and will not be made.
- ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
- ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
- ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

- ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
- ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
- ☐ A preliminary amendment.
- ☒ An Application Data Sheet under 37 CFR 1.76.
- ☒ A substitute specification.
- ☐ A power of attorney and/or change of address letter.
- ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
- ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
- ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
- ☒ Other items or information: Return Receipt Postcard
Marked-Up Specification

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known) see 37 CFR 1.51 <div style="font-size: 2em; font-weight: bold; margin-left: 100px;">10/516423</div>		INTERNATIONAL APPLICATION NO. PCT/SE03/00857		ATTORNEY'S DOCKET NUMBER ASZD-P01-708							
21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$1110.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$950.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$790.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$750.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 <div style="text-align: center;">ENTER APPROPRIATE BASIC FEE AMOUNT =</div> Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				CALCULATIONS PTO USE ONLY <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; border: none;">\$</td> <td style="width: 20%; border: none; text-align: right;">1,110.00</td> <td style="width: 20%; border: 1px solid black;"></td> </tr> <tr> <td style="border: none;">\$</td> <td style="border: none;"></td> <td style="border: 1px solid black;"></td> </tr> </table>		\$	1,110.00		\$		
\$	1,110.00										
\$											
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE								
Total claims	-20 =		x	\$							
Independent claims	-3 =		x	\$							
MULTIPLE DEPENDENT CLAIM(s) (if applicable)				+	\$						
TOTAL OF ABOVE CALCULATIONS =				\$	1,110.00						
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$							
SUBTOTAL =				\$	1,110.00						
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				\$							
TOTAL NATIONAL FEE =				\$	1,110.00						
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$							
TOTAL FEES ENCLOSED =				\$	1,110.00						
				Amount to be refunded:	\$						
				Amount to be charged:	\$						
a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed. b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>18-1945</u> in the amount of \$ <u>1,110.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>18-1945</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.											
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.											
SEND ALL CORRESPONDENCE TO: Patricia Granahan, Sc.D. ROPES & GRAY LLP One International Place Boston, Massachusetts 02110-2624 (617) 951-7449 CUSTOMER NUMBER: 28120											
				SIGNATURE:	<u>David P. Halstead</u>						
				NAME	<u>44,735</u>						
				REGISTRATION NUMBER							

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DT09 Rec'd PCT/PTO 29 NOV 2004

Application No. (if known): Not Yet Assigned

Attorney Docket No.: ASZD-P01-708

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV543609565US in an envelope addressed to:

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on November 29, 2004
Date



Signature

Andrea Berlo

Typed or printed name of person signing Certificate

Registration Number, if applicable

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Transmittal Letter to the United States Designated-Elected Office (2 pages)
Application Data Sheet (3 pages)
Marked-Up Specification (103 pages)
Substitute Specification (102 pages)
Copy of PCT/SE03/00857
Return receipt postcard